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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/574,527	05/22/2007	Christopher L. Hall	UMIC:050US	6982		
32425	7590	02/24/2009	EXAMINER			
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701				GAMETT, DANIEL C		
ART UNIT		PAPER NUMBER				
1647						
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/574,527	HALL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DANIEL C. GAMETT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 May 2007.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 31 March 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/05/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

1. The preliminary amendments of 05/22/2007 have been entered in full. Claims 24-30 are cancelled. Claims 1-23 are under examination.
  
2. Claim 20 recites the limitation, "wherein said osteoblast is not located in a subject". Claims 21 and 22 are dependent from claim 20 and they recite further limitations to the "subject". Although this does not give cause for an objection or rejection, it does raise a question of what the purpose would be to further define a subject when the target cell is not in the subject. Applicants should consider whether the intent was to have claims 21 and 22 depend from claim 19.

### ***Claim Objections***

3. Claims 17 and 18 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 3 and 4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 17 is identical to claim 3. Claim 18 is identically dependent from claim 17 as claim 4 is dependent from claim 3.
  
4. Claim 11 is objected to because of the following informalities: Misspelling: "...medium conditioned by growth of a metastatic prostate cancer cell therein". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is insufficient antecedent basis the limitation "said stem cell" in step (b); step (a) provides only an osteoblast cell.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kimura *et al.*, Urologia Internationalis, 48(1):25-30, 1992 (of record). Claim 11 is drawn to a composition comprising medium condition by growth of a metastatic prostate cancer cell therein. Kimura *et al.* teach a composition comprising medium that had been conditioned by PC-3 prostate cancer cells together with prostatic acid phosphatase and its substrate, alpha-glycerophosphate (see abstract). This composition fully anticipates the composition of claim 11. Furthermore, the Kimura *et al.* used the composition to stimulate the calcification of

human osteoblastic cells (see abstract), thereby practicing the method of instant claim 16, which is interpreted as requiring only that an osteoblast is contacted with at least one factor produced by a metastatic prostate cancer cell.

9. Claims 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Festuccia *et al.*, Oncology Research, 9(8):419-431 (1997) (of record). Festuccia *et al.* evaluated the biologic activities secreted into the supernatant from tissue cultures of human prostatic cancer cells on osteoblast-like cells in vitro (see Abstract). The conditioned medium disclosed by Festuccia *et al.* fully anticipates the composition of claim 11. The conditioned medium induced expression of alkaline phosphatase, thereby indicating that it promoted osteogenic differentiation (Figure 3 and 5). Therefore, by Festuccia *et al.* performed the method of instant claim 16, which is interpreted as requiring only that an osteoblast is contacted with at least one factor produced by a metastatic prostate cancer cell.

#### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 1-10, 12-15, and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura *et al.*, Urologia Internationalis, 48(1):25-30, 1992, or Festuccia *et al.*, Oncology

Research, 9(8):419-431 (1997), as applied to claims 11 and 16 above, and further in view of Boyce *et al.*, Endocrine-Related Cancer, 6:333-347 (1999), US Patent No. 5171579, December 15, 1992, US Patent No. 5736396, April 7, 1998, and WO 9833515 A1, August 16, 1998.

12. Claim 1 is drawn to a method of inducing a stem cell to undergo osteogenic differentiation comprising two steps: (a) providing a stem cell; and (b) contacting said stem cell with at least one factor produced by a metastatic prostate cancer cell under conditions supporting growth of said stem cell. As noted, both Kimura *et al.* and Festuccia *et al.* teach that medium conditioned by prostate cancer cells contains a factor or factors that promote osteogenic differentiation of osteoblasts, thereby anticipating the composition of claim 11 and the method of claim 16. Neither Kimura *et al.* nor Festuccia *et al.* teaches that the cell responding to the factors in conditioned medium is a stem cell, as recited in claim 1 and its dependents. Boyce *et al.* teach that prostate cancer cells secrete several specific factors that stimulate bone formation, including for example, BMPs, FGF, and prostaglandins (Table 2; final paragraph on page 341, first paragraph on page 342). US Patent No. 5171579 teaches that BMPs stimulate the osteogenic activity of progenitor cells from blood (claim 20; paragraph bridging columns 1 and 2). US Patent No. 5736396, citing earlier work, teaches that bone morphogenic proteins, such as BMP-2 and BMP-3, basic fibroblast growth factor (bFGF) and prostaglandins are factors which stimulate osteogenesis of isolated human mesenchymal stem cells (column 8, lines 6-13). WO 9833515 similarly teaches that BMP-2 and bFGF stimulate osteogenic differentiation of mesenchymal stem cells; this publication

specifically teaches the formation of bone nodules, which are tissue-like aggregates as recited in claim 5 and 6.

13. Therefore, in view of Boyce *et al.*, osteogenic factors in medium conditioned by prostate cancer cells have been positively identified. The '578 and '396 patents and WO 9833515 make it clear that these identified factors act upon stem cells from blood and bone marrow to promote osteogenic differentiation. Furthermore, as BMPs and FGFs are proteins ('heat-labile' as in claim 14), it is obvious that a step in their isolation from conditioned medium would be separation of protein from non-protein components, as recited in claims 13 and 15. It would be obvious to combine the osteogenic factors from medium conditioned by prostate cancer cells with any other known osteogenic factor (as in claims 10 and 23) because it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

14. In the absence of recitation of any specific, previously unidentified, component in medium conditioned by prostate cancer cells, the instantly claimed methods simply combine prior art elements according to known methods to yield predictable results. The Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398 at, 82 USPQ2d at 1395.

***Conclusion***

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/  
Examiner, Art Unit 1647